DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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APR - 3 1998

WARNING LETTER

VIA FEDERAL EXPRESS

David Schick
President and Chief Executive Officer
Schick Technologies, Inc.
31-00 47th Avenue
Long Island City, New York 11101

Dear Mr. Schick:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed a press release appearing on Schick Technologies, Inc.'s (Schick's) Internet website and pertaining to the company's accuDEXA™ Bone Mineral Density (BMD) Assessment System (accuDEXA). We have also reviewed a piece of the company's promotional labeling. The accuDEXA is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The accuDEXA was cleared pursuant to the 510(k) premarket notification process. The intended use, as stated in your 510(k) submission k971735, reads as follows: "The accuDEXA is a dual-energy x-ray device indicated for use in estimating the bone density of the middle finger of the non-dominant hand (BMD). This BMD value is a relative indicator of bone density elsewhere in the body."

The promotional materials and website press release have misbranded and adulterated your device within the meaning of sections 502(o) and 501(f)(1)(B), respectively, of the Act. The promotional piece is a light orange one page document entitled "accuDEXA BMD Assessment System" and claiming "Phalangeal BMD Predicts Hip and Spine Fracture." The press release is dated December 2, 1997 and appears on your website as of March 23, 1998.

The promotional piece makes repeated claims for fracture risk, i.e., hip and vertebral, and vertebral deformation. It also makes a claim for diagnosis of osteoporosis. The press release makes claims for predicting hip fracture risk and skeletal deformation. It also makes claims for diagnosing osteoporosis. Another item on your website is a description of the accuDEXA product. It claims, "Results are printed out, and you're ready to diagnose." This implies that you can diagnose osteoporosis with the results of the accuDEXA test.

On September 25, 1997, CDRH's Office of Device Evaluation issued a notice to industry stating that manufacturers wishing to market bone densitometers with a claim for determining fracture risk could do so using the Norland Model 178 bone densitometer as a predicate device. The required 510(k) premarket notification submission for such a device claim would have to establish that the device is substantially equivalent to the predicate for that claim. It would also have to include patient labeling explaining several aspects of osteoporosis and the measurement of bone density. Your 510(k) submission does not include information to support a claim for prediction of fracture risk or diagnosis of osteoporosis.

The agency's regulations at 21 CFR 801.4 provide that the term 'intended use" refers to the objective intent of the persons responsible for the labeling of the product. The intent can be shown in oral or written statements, labeling or advertising matter. Schick's materials have changed the intended use of the accuDEXA.

FDA's regulations at 21 CFR 807.81(a)(3)(ii) provide that a major change or modification in the intended use of a device currently in commercial distribution requires premarket notification. The device is misbranded within the meaning of section 502(o) of the Act in that a notice or other information respecting the device was not submitted in accordance with the requirements of section 510(k) of the Act. It is adulterated in that it is a class III device without either an approved premarket approval application in effect as required by section 515 of the act or an approved investigational device exemption as required by section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional and advertising materials used by your firm. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please advise this office in writing within 15 working days of your receipt of this letter what steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the Director, New York District Office (HFR- NE140), Food and Drug Administration, 850 3rd Avenue, Brooklyn, New York 11232-1593.

Sincerely yours,

Byron Tart for

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health